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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,573	04/19/2000	Gary K. Michelson M.D.	101.0077-00000	3776

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,573

Applicant(s)

MICHELSON M.D., GARY K.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2004 and 30 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-34,36-42 and 101-174 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-34,36-42 and 101-174 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Species 1 (figure 9A) in the reply filed on 11/30/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 3 has been withdrawn to a non-elected species.

Drawings

The drawings were received on 4/24/04. These drawings are accepted by the Examiner.

Response to Arguments

Applicant's arguments filed 4/24/04 have been fully considered. Regarding the rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the limitation, "*maximum dimension*" is not intended to describe the measurement between the side wall is greater than the measurement between the leading and trailing ends but simple state there is a maximum dimension in that direction.

Applicant's exhibit B showing at least claims 8 and 9 is appreciated, however, they are still not understood. It is unclear how applicant is forming a demarcation and how a single figure can show both "less than half" and "more than half".

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Kuntz (4,349,921), applicant argues that Michelson

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already teaches modular implants which are inserted separately into the disc space.

The Examiner does note this teaching and further notes the teaching that their insertion end may be bullet shape or a convexity', see column 10, lines 35 et seq. The reasons for combining the references is clearly stated in the grounds of rejection: "*It would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Michelson because "when a prosthesis for the lumbar area is required, it has been found advantages to make the prosthesis in two halves.." see column 9, lines 41 et seq."*

In response to applicant's arguments, section B, against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding applicant's arguments, section C, the combination which divides the implant of Michelson in half does produce an implant with a first distance greater than the second distance because of the actuate configuration of Michelson.

Specification

The amendment filed 9/11/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The new limitation added

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to page 17, line 6, describing the opposed portions of the implant can be in a moveable relationship is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 (and duplicates) rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The embodiments taught in this application do not have opposed portions which are moveable to adjust angulation of adjacent vertebral bodies. This claim limitation is not enabled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 8 and 9 are not understood. Same for claims 105-106. Please explain.

Applicant's explanation is appreciated, however, the limitation is still not understood.

Please diagram.

Claims 39 and similar, moveable relationship is not understood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-34, 36-42, and 101-174 (all elected claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (6,113,638) in view of Brantigan (5,192,327).

Williams et al teaches various spinal implants which conform to the anatomic contour of the vertebrae comprising an asymmetrical leading end, trailing end, and opposed portions (top and bottom) having at least a non-arcuate portion. Williams further teaches dividing the implant into halves as shown in figure 2 and described in column 5, lines 51 et seq. However, it is unclear upon dividing the implant into halves if an interior facing side wall is formed (and having an inner facing surfaces as only required in claim 1).

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Brantigan teaches a similar spinal implant and like Williams teaches the implant can be divide into halves as shown in figure 2 wherein an interior side wall 21c is formed. It would have been obvious to one having ordinary skill in the art to have used the teachings of Brantigan wherein an interior side wall is formed upon dividing the implant in two halves giving better structural integrity and to better contain grafting material.

Note figures 5-8 of Williams et al teach moveable opposing surfaces.

All other limitations are believed self-evident (or well known in the art).

Claims 1-2, 4-34, 36-42, and 101-174 (all elected claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Kuntz (4,349,921).

Referring to figures 1-17, Michelson teaches a spinal implant having an anterior aspect, a posterior aspect, and sidewalls. Michelson further teaches opposed surfaces having at least one opening and said opposed surfaces can be relatively angled. Michelson further teaches all claimed surfaces, elements, and material. However, Michelson does not teach the implant being less than approximately one-half the maximum width of the adjacent vertebrae.

Kuntz teaches a spinal implant can be formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6. It would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of

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Michelson because "*when a prosthesis for the lumbar area is required, it has been found advantages to make the prosthesis in two halves..*" see column 9, lines 41 **et seq.** In dividing the implant in two halves, it would have been obvious to one having ordinary skill in the art that in some embodiments, interior walls would be formed for structural integrity.

Note figures 12-14 of Kuntz teaching moveable opposing surfaces.

Regarding new claims 154-156 and 163-165, note the trailing end of Michelson has a rounded outside corner fulfilling the claim language.

Conclusion

Applicant's amendment including the amendments to claims 102 and 147 and the addition of new claims 156-174 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

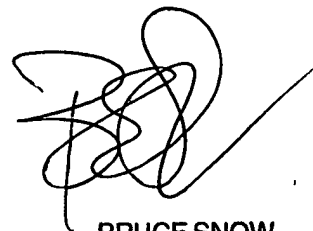
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER